

青岛未来医得咨询有限公司

wemdr.com

我们致力于为医疗器械制造商提供专业化、职业化和差异化的基于标准的全套 CE/FDA 整体解决方案，包括管理体系的审核、医疗器械（包括 III 类）的 CE / FDA 认证服务及培训服务，以及产品检测服务等。

- 我们敢于承诺：由于我方原因而未能取得证书，**全额退款（含 III 类）**。
- 我们的专家团队成员来自：美国，加拿大，英国，中国。
- 我们免费提供大量的医疗器械国际标准、行业标准，欧盟协调标准供大家学习交流。
- 我的服务：

青岛未来医得咨询		WEMDR. 医得
		www.wemdr.com
		wemdr-BJ-01
编号	项目	咨询包含内容
1	ISO 13485(医疗器械质量体系认证)	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
2	ISO 9001（质量体系认证QMS）	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
3	德国	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
4	ISO 13485(医疗器械质量体系认证)和ISO9001	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
5	ISO 13485(医疗器械质量体系认证)	质量手册和程序文件，协助完成第三层和第四层文件的完善
6	CE(IIa)	全套文件
7	CE(IIb)	全套文件
8	CE(III)	全套文件
9	国内注册（二类）	全套文件
10	国内三类	全套文件除临床
11	灭菌确认	灭菌确认方案、报告（安装鉴定IQ\运行鉴定OQ\性能鉴定PQ）、记录、不合格项的整改
12	包装确认	包装确认包括热封确认、加速老化确认
13	模拟运输确认	按照astmD4169出具包括方案、检测报告、确认报告
14	生物学评价	生物学评价报告
15	临床评价报告	方案报告
16	上市后产品监督计划（PMCF）	
17	上市后产品报告	上市后产品报告
18	易用性（可用性）报告	IEC_62366-可用性报告
19	风险管理报告（CE）	符合ISO 14971要求的风险分析报告
20	风险管理报告（国内）	
21	工艺用水确认报告	符合国内医疗器械规范（医疗器械gmp）的方案报告等
22	飞行检查符合性（国内）	检查符合性、不合格整改，让企业符合gmp规范，避免停产
23	确认培训（灭菌、包装、工艺用水、热封、CE法规）	培训ppt，课程1-2天
24	国内医疗器械飞检培训	课程1-2天
25	降解方案及报告	编写降解方案（符合国内、ce、FDA要求），检测报告



Standard Test Method for Compression-Displacement of Baseballs and Softballs¹

This standard is issued under the fixed designation F1888; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method describes a comparative measurement method for baseballs and softballs as defined by a static compression displacement test.

1.2 This test method is based on a slow rate force-displacement measurement.

1.3 This procedure is for baseballs and softballs meeting standards established by the sports' governing bodies.

NOTE 1—Since the compression-displacement of baseballs and softballs can influence the performance characteristics, this test provides a simple method to compare and categorize such balls based on force levels in a standardized compression-displacement test.

1.4 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*²

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *baseballs and softballs, n*—any such ball defined by the rules of the game as published by the sports' governing bodies.

¹ This test method is under the jurisdiction of ASTM Committee F08 on Sports Equipment, Playing Surfaces, and Facilities and is the direct responsibility of Subcommittee F08.26 on Baseball and Softball Equipment.

Current edition approved Aug. 1, 2016. Published August 2016. Originally approved in 1998. Last previous edition approved in 2014 as F1888 – 09 (2014). DOI: 10.1520/F1888-09R16.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3.1.2 *compression-displacement, n*—the reduction in ball diameter under a specified compressive load between two flat plates. Synonymous with *compression-deflection*.

3.1.3 *force, n*—the resistance to displacement. The interaction between test machine and ball during compression.

3.1.4 *four seams, n*—plane passing through the middle of the ball intersecting four stitch lines.

3.1.5 *two seams, n*—plane passing through the middle of the ball intersecting two stitch lines.

4. Summary of Test Method

4.1 The baseball or softball is placed between two flat-plate surfaces of a compression machine and then compressed to a standard displacement of 0.25 in. (6.35 mm). The compression load (force) applied at the standard displacement is recorded.

5. Significance and Use

5.1 The static compression-displacement of a baseball or softball is a mechanical property which can correlate to dynamic properties.

5.2 This test method is suitable for obtaining data in research and development, quality control, and classifying balls by the compression-displacement.

5.3 Sports associations can use compression-displacement standards in specifications for official baseballs and softballs for purposes of consistency of performance.

5.4 This same test procedure can be utilized with other compressive forces and the specified force is not necessarily the same as experienced in actual use.

6. Apparatus

6.1 *Compression Device*, to compress the test ball between two flat plates to 0.25 in. (6.35 mm) displacement. Compressive force to 800 lb (3560 N) is sufficient. A means of centering the test ball so that the vertical axis of the ball aligns with the vertical axis of the compression device piston.

6.2 *Compression Force Gauge*, to measure the compressive load in newtons or pounds. Device must be able to measure at least 1000 lb (4448 N).

6.3 *Compression-Displacement Gauge*, to measure the displacement at the prescribed level of 0.25 in. (6.35 mm).

6.4 *Motor, Drive, and Speed Control*, to drive the compression device to 0.25 in. (6.35 mm) displacement in a time of 12 to 18 s at a constant rate.

6.5 *A Steel Tape*, 0.25 in. (6.35 mm) wide, suitable for measuring lengths to the nearest 0.0625 in. (1.5875 mm).

7. Conditioning

7.1 *Ball Conditioning and Test Room Conditions*:

7.1.1 Test balls shall be stored in an environmentally controlled space for at least 14 days immediately before testing.

7.1.2 Temperature is to be maintained at $72 \pm 4^\circ\text{F}$ ($22 \pm 2^\circ\text{C}$).

7.1.3 Relative humidity is to be maintained at between 40 and 60 %.

7.1.4 Temperature and humidity are to be measured and recorded hourly within $\pm 0.5^\circ\text{F}$ ($\pm 0.3^\circ\text{C}$) and $\pm 2\%$ RH over conditioning and test duration.

8. Procedure

8.1 Wrap the steel tape around the middle of the ball to measure the circumference twice over two seams (each measurement taken 90° apart) and once over four seams. Record data to the nearest 0.0625 in. (1.5875 mm). Average the three measurements to obtain the final size measurement.

8.2 Orient the ball in the compression press to align the vertical axis of the ball with the vertical axis of the compressing piston, and orient the ball so that compression occurs between ball seams.

8.3 Activate the compression press until the upper plate is in contact with the ball with a 1-lb (4.45-N) preload for expected compression values less than 150 lb (667.5 N) $\pm 5\%$ and a 4-lb (17.8-N) preload for expected compression values greater than 150 lb (667.5 N) $\pm 5\%$ applied to the ball.

8.4 Set the compression displacement gage reading to zero.

8.5 Compress the ball to a displacement of 0.25 in. (6.35 mm) in 12 to 18 s at a constant rate and record the peak force applied at that level of displacement.

8.6 Release the applied load, rotate the ball 90° and repeat 8.2 – 8.5.

NOTE 2—Depending on the materials of construction, the compression-displacement may change with repeated compressions. For this reason, the procedure is limited to two compressions, on two different axis of the test balls.

9. Calculation

9.1 Ball compression is calculated as the average of the two measured forces required to compress the test ball 0.25 in. (6.35 mm) on two different axis of the ball.

10. Report

10.1 Report the following information:

10.1.1 Name of the test facility and test operator,

10.1.2 Test date,

10.1.3 Hourly measurements of test conditions, including:

10.1.3.1 Relative humidity and temperature of the ball conditioning and test room environments,

10.1.3.2 Number of hours ball was in conditioning environment.

10.1.4 Test equipment used for this test method,

10.1.5 Test ball information, model, weight tested, and any other pertinent data such as condition of the ball,

10.1.6 Average ball compression in accordance with Section 9 of this standard.

10.1.7 Any and all unique observations, including but not exclusively, any damage to the ball, and

10.1.8 Calibration certificate numbers for measurement devices.

11. Precision and Bias³

11.1 The precision of this test method is based on an interlaboratory study conducted in 2008. Each of six laboratories tested ten different baseballs. Every “test result” represents an individual determination. Each laboratory reported three replicate test results for the analyses. Practice E691 was followed for the design and analysis of the data; the details are given in the research report footnoted above.

11.1.1 *Repeatability Limit (r)*—Two test results obtained within one laboratory shall be judged not equivalent if they differ by more than the “*r*” value for that material; “*r*” is the interval representing the critical difference between two test results for the same material, obtained by the same operator using the same equipment on the same day in the same laboratory.

11.1.1.1 Repeatability limits are listed in Table 1.

11.1.2 *Reproducibility Limit (R)*—Two test results shall be judged not equivalent if they differ by more than the “*R*” value for that material; “*R*” is the interval representing the critical difference between two test results for the same material, obtained by different operators using different equipment in different laboratories.

11.1.2.1 Reproducibility limits are listed in Table 1.

11.1.3 The terms repeatability limit and reproducibility limit are used as specified in Practice E177.

11.1.4 Any judgment in accordance with statements 11.1.1 and 11.1.2 would have an approximate 95 % probability of being correct.

12. Keywords

12.1 baseballs; compression-displacement; softballs

³ Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:F08-1009.

TABLE 1 Compression (lb)

Ball	Average, x	Repeatability Standard Deviation, S_r	Reproducibility Standard Deviation, S_R	Repeatability Limit, r	Reproducibility Limit, R
Ball 1	206.65	11.95	22.36	33.45	62.61
Ball 2	205.40	13.27	20.52	37.17	57.45
Ball 3	206.50	14.68	27.38	41.11	76.68
Ball 4	203.47	14.30	19.42	40.05	54.37
Ball 5	213.07	14.38	20.01	40.26	56.03
Ball 6	211.52	11.04	25.40	30.92	71.11
Ball 7	225.49	16.86	27.46	47.20	76.88
Ball 8	222.92	12.18	21.43	34.11	60.01
Ball 9	220.54	13.63	26.70	38.18	74.76
Ball 10	219.45	12.50	25.19	35.01	70.52
Average	213.50	13.48	23.59	37.75	66.04

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org). Permission rights to photocopy the standard may also be secured from the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, Tel: (978) 646-2600; <http://www.copyright.com/>